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K000591

II. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Name:.....ESPE Dental AG

Street:.....ESPE Platz

ZIP-Code, City:.....D-82229 Seefeld

Federal State:.....Bavaria

Country:.....Germany

Establishment Registration Number:....9611385

Contact:.....Dr. Andreas Petermann, Manager U.S. Regulatory Affairs

Phone:.....011-49-8152-7001395

Fax:.....011-49-8152-7001869

E-mail.....Andreas_Petermann@ESPE.de

Date:.....February 16, 2000

Name of Devices

Proprietary Name:.....DIMENSION® PENTA® H
DIMENSION® PENTA® H QUICK

Classification Name:.....Impression material

Common Name:.....Polyvinyl siloxane based impression material

Predicate Devices

DIMENSION® PENTA®
DIMENSION® GARANT® L by ESPE.....K 960547

Description for the Premarket Notification

DIMENSION® PENTA® H and DIMENSION® PENTA® H QUICK are classified as impression materials (21 C.F.R. § 872.3660) because they are devices intended to reproduce the structure of a patient's teeth.

DIMENSION® PENTA® H and DIMENSION® PENTA® H QUICK are high consistency impression materials designed to be used as tray material in dual phase impression technique. Therefore, both are similar in intended use and substantially equivalent to ESPE's polyvinylsiloxane based impression material DIMENSION® PENTA.

DIMENSION® PENTA® H and DIMENSION® PENTA® H Quick are two-component materials (base paste and catalyst) packaged in polybags which are intended to be mixed in ESPE's automatic mixing, dosing and dispensing system PENTAMIX® 2. PENTAMIX® 2 received 510(k) clearance on July 26, 1999 (K 991913).

In recent years ESPE was already marketing high consistency impression materials tradenamed DIMENSION® PENTA® H and DIMENSION® PENTA® H QUICK in U.S.A. The marketing of these materials was based on the 510(k) for DIMENSION® PENTA® (K 960547). Actually, the name DIMENSION® PENTA® was changed into DIMENSION® PENTA® H to distinguish that material from DIMENSION® PENTA® L, a low viscosity material. The name change and the development of a fast setting variant, DIMENSION® PENTA® H QUICK was considered to not requiring the submission of a new 510(k) premarket notification because the chemical composition was only changed slightly and the indications for use were not affected.

However, in this 510(k) premarket notification submission the latest DIMENSION® PENTA® H generation is described in terms of chemical composition and physical and mechanical properties. Furthermore, the range of indications will no longer be limited to impressions for inlay, onlay, crown and bridge preparations and impressions of edentulous jaws. The range of indications will be expanded to allow all types of dual phase impressions, e.g. also for orthodontics.

DIMENSION® PENTA® H and DIMENSION® PENTA® H QUICK have the following similarities to the 510(k)ed DIMENSION® PENTA®:

- DIMENSION® PENTA® H and DIMENSION® PENTA® H QUICK are used by the same operating principle

- DIMENSION® PENTA® H and DIMENSION® PENTA® H QUICK incorporate the same basic chemical design
- DIMENSION® PENTA® H and DIMENSION® PENTA® H QUICK have the same shelf life
- DIMENSION® PENTA® H and DIMENSION® PENTA® H QUICK are manufactured and packaged using the same materials and processes

The physical and mechanical properties of the new DIMENSION® PENTA® H and DIMENSION® PENTA® H QUICK have been compared to those of the old DIMENSION® PENTA®.

The compositions of DIMENSION® PENTA® H and DIMENSION® PENTA® H QUICK contain the same ingredients as ESPE's DIMENSION® PENTA® impression material, variations only occur in quantitative terms. Therefore, additional biocompatibility testing is not necessary in our point of view.

ESPE's impression material DIMENSION® PENTA® is well established and considered to be safe and effective. Comparation of chemical constitution and physical and mechanical properties show that the new materials DIMENSION® PENTA® H and DIMENSION® PENTA® H QUICK are substantially equivalent to the well established material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dr. Andreas Petermann
Manager U.S. Regulatory Affairs
ESPE Dental AG
ESPE Platz
D-82229 Seefeld, Bavaria
GERMANY

Re: K000591
Trade Name: Dimension® Penta® H, Dimension® Penta® H Quick
Regulatory Class: II
Product Code: ELW
Dated: February 16, 2000
Received: February 22, 2000

Dear Dr. Petermann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000591 K000591

III. STATEMENT OF INDICATIONS FOR USE

Device Name:

DIMENSION® PENTA® H
DIMENSION® PENTA® H QUICK

Indications for use:

Dental impression material for automatic mixing and dispensing in a PENTAMIX® or PENTAMIX® 2 mixing device, resp.:

Tray material for all kinds of dual phase impression techniques

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000591